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Helen C. Lockhart
c/o Wolf, Greenfield & Sacks, P.C.,
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

EXAMINER

MUMMERT, STEPHANIE KANE

ART UNIT

PAPER NUMBER

1637

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,968

Applicant(s)

CHAN, EUGENE Y.

Examiner

Stephanie K. Mummert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 23-83 and 89-157 is/are pending in the application.
- 4a) Of the above claim(s) 23-87, 89-114, 125-129, 157 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 98, 115-124 and 130-156 and 161 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's election with traverse of Group 1, claims 1, 2, 98, 115-124 and 130-156 in the reply filed on October 28, 2005 is acknowledged. The traversal is on the ground(s) that search and examination of all of the groups would not pose an undue burden. This is not found persuasive because the previously filed restriction requirement establishes that there is a distinct and serious search burden placed on the examiner if the examiner were to examine all of the claims of the separate and distinct groups of inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 23-87, 89-114, 125-129, 157 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 28, 2005.

The amendment to the claims filed with the response to the restriction requirement adding claim 161 is acknowledged.

Claims 1, 2, 98, 115-124 and 130-156 and 161 are pending and will be examined.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on February 28, 2002 and the IDS filed on July 7, 2001 were filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

3. Claim 123 is objected to because of the following informalities: The term “lineally” appears to be a typographical error, replacing the term “linearly”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 121 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The phrase “...polymer dependent impulses include an order of polymer dependent impulses” is vague and indefinite because it is uncertain how to interpret the term “an order.” Is the term intended to refer to an order of magnitude, or is the term intended to refer to a collection of impulses recorded in sequential order as the monomer units pass by the station?

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 98 is rejected under 35 U.S.C. 102(b) as being anticipated by Mergny et al. (1994, Nucleic Acids Research, 23(6): 920-928). Mergny discloses a method for analysis of the formation of secondary hairpin structures through hybridization of two complementary oligonucleotide probes, followed by analysis of fluorescence energy transfer between the fluorophores attached to the probes (Abstract).

With regard to claim 98, Mergny discloses a method for detecting resonance energy transfer or quenching between two interactive partners capable of such transfer or quenching comprising: a) bringing the two partners in close enough proximity to permit such transfer or quenching (Figure 2, where oligonucleotide partners are designed to hybridize adjacent to one another on a target nucleic acid, leading to transfer; see also Figure 4 and 5, where variations of the basic hybridization assay of Figure 2 are tested);

b) applying an agent to one of said partners, the agent selected from the group consisting of electromagnetic radiation, a quenching source, and a fluorescence excitation source (p. 922, col. 1 'spectroscopic studies' heading, where the agent was a fluorescence excitation source applied by a Spex Fluorolog DM1B instrument and where emission wavelength was chosen according to the donor-acceptor couple);

c) shielding fluorescence resonance energy transfer and quenching occurring from electromagnetic radiation emission and interaction between said partners with a material shield (p. 922, col. 1, 'spectroscopic studies' heading, where the transfer is shielded by a quartz cuvette); and

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d) detecting the emitted electromagnetic radiation (p. 922, col. 1, 'spectroscopic studies' heading, where measurements were performed on a Spex Fluorolog DM1B instrument, with a bandwidth of 1.8 nm and where correction of emission spectra was obtained by recording the spectra of samples and standards and correcting for absorbance differences).

9. Claims 1-2, 130-133, 135-142, 144-146, 149-152, 154-156 and 161 are rejected under 35 U.S.C. 102(b) as being anticipated by Yeung et al. (US Patent 5,324,401; June 1994). Yeung discloses a method and apparatus for capillary electrophoresis and sequencing of polymers (Abstract).

With regard to claim 1, Yeung discloses a method for identifying an individual unit of polymer comprising - a) transiently moving the individual unit of the polymer relative to a station, the identity of the individual unit being unknown (col. 6, lines 33-47, where the samples are moved through the array from a high voltage end to a low voltage end);

b) detecting a signal arising from a detectable physical change in the unit or the station (col. 6, lines 63-65, where an excitation laser is coupled to the optical fibers within the capillaries and col. 7, lines 7-12, where fluorescent light emitted from fluorescent species is imaged through the means of an adapter and onto a charge-coupled device); and

c) distinguishing said signal from signals arising from exposure to adjacent signal generating units of the polymer to the station as an indication of the identity of the individual unit (Examples 2 and 3, where DNA sequences were obtained).

With regard to claim 2, Yeung discloses an embodiment of claim 1, wherein the station is an interaction station and wherein individual units are exposed at the interaction station to an

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agent that interacts with the individual unit to produce a detectable electromagnetic radiation signal characteristic of said interaction (col. 5, lines 33-37, where a laser can simultaneously excite fluorescence in multiple capillaries and a detector can also simultaneously monitor separation of analytes).

With regard to claim 161, Yeung discloses an embodiment of claim 1, wherein the station is a signal generation station and the signal produced is a polymer dependent impulse (col. 5, lines 33-37, where a laser can simultaneously excite fluorescence in multiple capillaries and a detector can also simultaneously monitor separation of analytes).

With regard to claim 130, Yeung discloses a method for determining the order of units of a polymer of linked units comprising:

- 1) moving the polymer linearly relative to a station (col. 3, lines 28-47, where polymers are analyzed in multiple capillaries arranged in an array and col. 6, lines 33-47, where the samples are moved through the array from a high voltage end to a low voltage end);
- 2) measuring a polymer dependent impulse generated as each of two individual units, each giving rise to a characteristic signal, pass by the station (col. 5, lines 33-37, where a laser can simultaneously excite fluorescence in multiple capillaries and a detector can also simultaneously monitor separation of analytes);
- 3) repeating steps 1 and 2 for a plurality of similar polymers; and
- 4) determining the order of at least two individual units based upon the information obtained from said plurality of similar polymers (Examples 2 and 3, where DNA sequences were obtained).

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With regard to claim 131, Yeung discloses an embodiment of claim 130, wherein the station is a signal generation station (col. 5, lines 33-37, where a laser can simultaneously excite fluorescence in multiple capillaries and a detector can also simultaneously monitor separation of analytes).

With regard to claim 132, Yeung discloses an embodiment of claim 130, wherein the station is an interaction station (col. 5, lines 33-37, where a laser can simultaneously excite fluorescence in multiple capillaries and a detector can also simultaneously monitor separation of analytes).

With regard to claim 133, Yeung discloses an embodiment of claim 130, wherein step 2) comprises measuring an electromagnetic radiation signal generated (col. 4 line 63 to col. 5, line 5, see col. 9 lines 9-25; see also Example 1, col. 15, lines 35-41).

With regard to claim 135, Yeung discloses an embodiment of claim 130, wherein the plurality of similar polymers is a heterogeneous population (col. 14, lines 7-30).

With regard to claim 136, Yeung discloses an embodiment of claim 130, wherein the polymer is a nucleic acid (col. 4, lines 55-60, where multiple types of polymers can be analyzed, including RNA and DNA).

With regard to claim 137, Yeung discloses a method for analyzing a set of polymers, each polymer of said set being an individual polymer of linked units comprising:

a) orienting the set of polymers parallel to one another (col. 3, lines 28-47, where polymers are analyzed in multiple capillaries arranged in an array and col. 6, lines 33-47, where the samples are moved through the array from a high voltage end to a low voltage end); and

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b) detecting a polymer specific feature of said polymers (col. 4 line 63 to col. 5, line 5, see col. 9 lines 9-25; see also Example 1, col. 15, lines 35-41).

With regard to claim 147, Yeung discloses a method for analyzing a set of polymers, each polymer of the set being an individual polymer of linked units, comprising:

- a) orienting the set of polymers in an electric field (col. 3, lines 28-47, where polymers are analyzed in multiple capillaries arranged in an array and col. 6, lines 33-47, where the samples are moved through the array from a high voltage end to a low voltage end);
- b) simultaneously moving the set of polymers through defined respective channels (col. 6, lines 33-47, where the samples are moved through the array from a high voltage end to a low voltage end and col. where the capillaries are defined channels, and col. 4, lines 24-28, where the array can include as many as 1000 capillaries); and
- c) detecting a polymer specific feature as polymers are moved through the channels (col. 4 line 63 to col. 5, line 5, see col. 9 lines 9-25; see also Example 1, col. 15, lines 35-41).

With regard to claim 138, Yeung discloses an embodiment of claim 137, wherein the polymers are oriented by applying an electric field to said polymers (col. 6, lines 33-47, where the samples are moved through the array from a high voltage end to a low voltage end; see also Example 1, col. 15, line 55-68, where the electrophoretic separation was driven at +7.5 kV using a high voltage power supply).

With regard to claim 139 and 149, Yeung discloses an embodiment of claim 137, wherein the polymer specific feature is an order of linked unity in the polymers (Examples 2 and 3, where DNA sequences were obtained).

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With regard to claim 140 and 150, Yeung discloses an embodiment of claim 137, wherein the detecting step is performed simultaneously for said polymers (col. 5, lines 33-37, where a laser can simultaneously excite fluorescence in multiple capillaries and a detector can also simultaneously monitor separation of analytes).

With regard to claim 141 and 151, Yeung discloses an embodiment of claim 137, wherein the detection step comprises measuring electromagnetic radiation signals (col. 4 line 63 to col. 5, line 5, see col. 9 lines 9-25; see also Example 1, col. 15, lines 35-41).

With regard to claims 142 and 152, Yeung discloses an embodiment of claim 137, wherein the detection step comprises causing the polymers to pass linearly relative to a plurality of signal generation stations, and detecting and distinguishing signals generated as said polymers pass said interaction stations (col. 6, lines 33-47, where the samples are moved through the array from a high voltage end to a low voltage end and col. where the capillaries are defined channels, and col. 4, lines 24-28, where the array can include as many as 1000 capillaries and col. 5, lines 33-37, where a laser can simultaneously excite fluorescence in multiple capillaries and a detector can also simultaneously monitor separation of analytes).

With regard to claims 144 and 154, Yeung discloses an embodiment of claim 137, wherein the polymers are a heterogeneous population (col. 14, lines 7-30).

With regard to claims 145 and 155, Yeung discloses an embodiment of claim 137, wherein the polymers are randomly labeled (col. 5 line 60 to col. 6, line 29 and col. 10, lines 30-42)

With regard to claims 146 and 156, Yeung discloses an embodiment of claim 137, wherein the orientation step is in a solution free of gel (col. 14, lines 31-49, where the invention is applicable to capillary zone electrophoresis, wherein a no gel is used).

With regard to claim 148, Yeung discloses an embodiment of claim 147, wherein the channels are nanochannels (col. 3, lines 48-53 and col. 9, lines 1-8, where capillaries of a diameter as small as 5 μm and as large as 500 μm were used).

10. Claims 1-2, 130-134, 137-143, 147-153 and 161 are rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al. (1992, Anal. Chem., 64, p. 2149-2154). Huang teaches a DNA sequencing method using capillary array electrophoresis (Abstract).

With regard to claim 1, Huang discloses a method for identifying an individual unit of polymer comprising - a) transiently moving the individual unit of the polymer relative to a station, the identity of the individual unit being unknown (Figure 1, where the capillaries are arranged linearly in relation to the detection station. In addition, p. 249, 'instrumentation' heading, where a stage is used to translate the array past the optical system at 20mm/s and fluorescence is sampled at 1500 Hz/channel);
b) detecting a signal arising from a detectable physical change in the unit or the station (p. 2149, col. 1, 'instrumentation' heading, where the capillaries are excited by an argon laser and fluorescence is collected by the objective and passed back through multiple stages to be stored on a computer); and

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c) distinguishing said signal from signals arising from exposure to adjacent signal generating units of the polymer to the station as an indication of the identity of the individual unit (Figure 4, where sequence of the polymers was obtained).

With regard to claim 2, Huang discloses an embodiment of claim 1, wherein the station is an interaction station and wherein individual units are exposed at the interaction station to an agent that interacts with the individual unit to produce a detectable electromagnetic radiation signal characteristic of said interaction (p. 2149, col. 1, 'instrumentation' heading, where the capillaries are excited by an argon laser and fluorescence is collected by the objective and passed back through multiple stages to be stored on a computer).

With regard to claim 161, Huang discloses an embodiment of claim 1, wherein the station is a signal generation station and the signal produced is a polymer dependent impulse (Figure 1, inset, where the capillaries are arranged side by side and the detection step is performed for each capillary simultaneously and where the capillaries are excited by an argon laser and fluorescence is collected by the objective and passed back through multiple stages to be stored on a computer).

With regard to claim 130, Huang discloses a method for determining the order of units of a polymer of linked units comprising:

1) moving the polymer linearly relative to a station (Figure 1, where the capillaries are arranged linearly in relation to the detection station. In addition, p. 249, 'instrumentation' heading, where a stage is used to translate the array past the optical system at 20mm/s and fluorescence is sampled at 1500 Hz/channel);

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- 2) measuring a polymer dependent impulse generated as each of two individual units, each giving rise to a characteristic signal, pass by the station (p. 2149, col. 1, 'instrumentation' heading, where the capillaries are excited by an argon laser and fluorescence is collected by the objective and passed back through multiple stages to be stored on a computer);
- 3) repeating steps 1 and 2 for a plurality of similar polymers; and
- 4) determining the order of at least two individual units based upon the information obtained from said plurality of similar polymers (Figure 4, where sequence of the polymers was obtained).

With regard to claim 131, Huang discloses an embodiment of claim 130, wherein the station is a signal generation station (Figure 1, inset, where the capillaries are arranged side by side and the detection step is performed for each capillary simultaneously and where the capillaries are excited by an argon laser and fluorescence is collected by the objective and passed back through multiple stages to be stored on a computer).

With regard to claim 132, Huang discloses an embodiment of claim 130, wherein the station is an interaction station (p. 2149, col. 1, 'instrumentation' heading, where the capillaries are excited by an argon laser and fluorescence is collected by the objective and passed back through multiple stages to be stored on a computer).

With regard to claim 133, Huang discloses an embodiment of claim 130, wherein step 2) comprises measuring an electromagnetic radiation signal generated (p. 2149, col. 1, 'instrumentation' heading, where the capillaries are excited by an argon laser and fluorescence is collected by the objective and passed back through multiple stages to be stored on a computer).

With regard to claim 134, Huang discloses an embodiment of claim 130, wherein the plurality of similar polymers is a homogeneous population (p. 2150, col. 1 'preparation of DNA

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sequencing sample' heading, where chain terminated M13mp18 DNA sequencing fragments were analyzed).

With regard to claim 136, Huang discloses an embodiment of claim 130, wherein the polymer is a nucleic acid (Abstract, p. 2149, col. 1, where the nucleic acid is DNA).

With regard to claim 137, Huang discloses a method for analyzing a set of polymers, each polymer of said set being an individual polymer of linked units comprising:

- a) orienting the set of polymers parallel to one another (Figure 1, where polymers were arranged in parallel within a grid holder, where capillaries were attached to the grid then as the capillaries stretch across the detector, the capillaries are flat parallel to one another); and
- b) detecting a polymer specific feature of said polymers (Figure 4, where sequence of the polymers was obtained).

With regard to claim 147, Huang discloses a method for analyzing a set of polymers, each polymer of the set being an individual polymer of linked units, comprising:

- a) orienting the set of polymers in an electric field (p. 2150, col. 1, top paragraph, where the polymers were oriented within the capillary with an applied electric field of $\sim 225\text{V/cm}$);
- b) simultaneously moving the set of polymers through defined respective channels (see Figure 1, where multiple capillaries, attached to an array, are loaded with polymer and the polymers are moved through the capillaries); and
- c) detecting a polymer specific feature as polymers are moved through the channels (Figure 4, where sequence of the polymers was obtained).

With regard to claim 138, Huang discloses an embodiment of claim 137, wherein the polymers are oriented by applying an electric field to said polymers (p. 2150, col. 1, top

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paragraph, where the polymers were oriented within the capillary with an applied electric field of $\sim 225\text{V/cm}$).

With regard to claim 139 and 149, Huang discloses an embodiment of claim 137, wherein the polymer specific feature is an order of linked unity in the polymers (Figure 4, where sequence of the polymers was obtained and where the sequence is determined in a linear fashion, including base composition and order of bases in relation to one another).

With regard to claim 140 and 150, Huang discloses an embodiment of claim 137, wherein the detecting step is performed simultaneously for said polymers (Figure 1, inset, where the capillaries are arranged side by side and the detection step is performed for each capillary simultaneously).

With regard to claim 141 and 151, Huang discloses an embodiment of claim 137, wherein the detection step comprises measuring electromagnetic radiation signals (p. 2149, col. 1, 'instrumentation' heading, where the capillaries are excited by an argon laser and fluorescence is collected by the objective and passed back through multiple stages to be stored on a computer).

With regard to claim 142 and 152, Huang discloses an embodiment of claim 137, wherein the detection step comprises causing the polymers to pass linearly relative to a plurality of signal generation stations, and detecting and distinguishing signals generated as said polymers pass said interaction stations (Figure 1, where the capillaries are arranged linearly in relation to the detection station. In addition, p. 249, 'instrumentation' heading, where a stage is used to translate the array past the optical system at 20mm/s and fluorescence is sampled at 1500Hz/channel).

With regard to claim 143 and 153, Huang discloses an embodiment of claim 137, wherein the polymers are a homogeneous population (p. 2150, col. 1 'preparation of DNA sequencing sample' heading, where chain terminated M13mp18 DNA sequencing fragments were analyzed).

With regard to claim 148, Huang discloses an embodiment of claim 147, wherein the channels are nanochannels (p. 2149, col. 2, 'preparation of capillary arrays' heading, where capillaries of 100 μm inner diameter were used).

11. Claims 1, 2, 115-124, 130-136 and 161 are rejected under 35 U.S.C. 102(e) as being anticipated by Church et al. (US Patent 5,795,782; August 1998). Church teaches a method for characterizing a linear polymer by measuring physical changes across an interface as the linear polymer traverses the interface and the monomers of the polymer interact with the interface (Abstract).

With regard to claim 1, Church discloses a method for identifying an individual unit of polymer comprising - a) transiently moving the individual unit of the polymer relative to a station, the identity of the individual unit being unknown (col. 3, line 66 to col. 4, line 4; see also, col. 1, lines 40-54, where the interface or station interacts sequentially with individual monomers of a polymer and col. 6, line 66 to col. 7, line 4, where the invention is primarily concerned with sequencing nucleic acids);

b) detecting a signal arising from a detectable physical change in the unit or the station (col. 2, line 21-34, where the measurements can be any measurement, e.g., physical or electrical, that varies with polymer-dependent interaction; see also col. 4, lines 31-37, where the characteristics

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of the polymer can be identified by the amplitude or duration of individual conductance changes across the passage; and see also col. 1, lines 40-54); and

c) distinguishing said signal from signals arising from exposure to adjacent signal generating units of the polymer to the station as an indication of the identity of the individual unit (col. 4, lines 31-37, where changes in conductance can identify the monomers in sequence because each monomer will have a characteristic conductance change signature).

With regard to claim 2, Church discloses an embodiment of claim 1, wherein the station is an interaction station and wherein individual units are exposed at the interaction station to an agent that interacts with the individual unit to produce a detectable electromagnetic radiation signal characteristic of said interaction (col. 3, line 66 to col. 4, line 4; see also, col. 1, lines 40-54, where the interface or station interacts sequentially with individual monomers of a polymer and would therefore meet the limitation of 'interaction station' and see col. 2, line 21-34, where the measurements can be any measurement, e.g., physical or electrical, that varies with polymer-dependent interaction).

With regard to claim 161, Church discloses an embodiment of claim 1, wherein the station is a signal generation station and the signal produced is a polymer dependent impulse (col. 4, lines 31-37, where changes in conductance can identify the monomers in sequence because each monomer will have a characteristic conductance change signature and where the signal generated by the interaction between the station and the monomer would meet the limitation of 'signal generation station').

With regard to claim 115, Church discloses a method for characterizing a test polymer comprising: a) obtaining polymer dependent impulses for a plurality of polymers (col. 1, line 66 to col. 2, line 8, where a heterogeneous population of polymers may be characterized); b) comparing the polymer dependent impulses of the plurality of polymers (col. 1, line 66 to col. 2, line 8, where a distribution of characteristics, such as size, is established for the population of polymers characterized); c) determining the relatedness of the polymers based upon similarities between the polymer dependent impulses of the polymers (col. 1, line 66 to col. 2, line 8, where a distribution of characteristics, such as size, is established for the population of polymers characterized and col. 4, line 51-56, where the mixture of polymers can be homogeneous or heterogeneous and yield a distribution of molecules of varying sizes with sequence data for multiple polymers); and d) characterizing the test polymer based upon the polymer dependent impulses of related polymers (col. 4, lines 40-50, where the conductance changes measured for a specific polymer can be compared to a polymer with a known sequence to determine the proportional relationship between the number of monomers and the number of monomer-dependent conductance changes).

With regard to claim 116, Church discloses an embodiment of claim 115, wherein the plurality of polymers is a homogeneous population (col. 4, lines 51-56).

With regard to claim 117, Church discloses an embodiment of claim 115, wherein the plurality of polymers is a heterogeneous population (col. 4, lines 51-56).

With regard to claim 119, Church discloses an embodiment of claim 115, wherein the polymer is a polymer of at least two different linked units and wherein said at least two different

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linked units are labeled to produce different signals (col. 7, line 61 to col. 8, line 20, where “the chemical composition of individual monomers is sufficiently variant to cause characteristic changes in channel conductance as each monomer traverses the pore...” however, “if the recording techniques are not sensitive enough to detect differences between normal bases in DNA, it is practical to supplement the system’s specificity by using modified bases” and where these bases would serve to produce distinguishable signals for each type of monomer).

With regard to claim 120, Church discloses an embodiment of claim 115, wherein the polymer is a nucleic acid (col. 1, lines 59-62).

With regard to claim 121, Church discloses an embodiment of claim 120, wherein the obtained polymer dependent impulses include an order of polymer dependent impulses (col. 1, line 66 to col. 2, line 8, where the number and composition of monomers that make up an individual polymer is determined, preferably in sequential order).

With regard to claim 122, Church discloses an embodiment of claim 120, wherein the obtained polymer dependent impulses includes one of time of separation between specific signals (col. 4, lines 31-44, where the length of time that monomer-dependent conductance changes occur).

With regard to claim 123, Church discloses an embodiment of claim 120, wherein the polymer dependent impulses are obtained by moving the plurality of polymers linearly past a signal generation station (col. 3, line 66 to col. 4, line 18, where the polymer moves in relation to the passage or station, where individual monomers interact with the interface to induce a change in conductance).

With regard to claim 124, Church discloses an embodiment of claim 120, wherein the obtained polymer dependent impulses include a number of polymer dependent impulses (col. 1, line 66 to col. 2, line 8, where the number and composition of monomers that make up an individual polymer is determined, preferably in sequential order).

With regard to claim 130, Church discloses a method for determining the order of units of a polymer of linked units comprising:

- 1) moving the polymer linearly relative to a station (col. 3, line 66 to col. 4, line 18, where the polymer moves in relation to the passage or station, where individual monomers interact with the interface to induce a change in conductance);
- 2) measuring a polymer dependent impulse generated as each of two individual units, each giving rise to a characteristic signal, pass by the station (col. 4, lines 31-40, where changes in conductance can identify the monomers in sequence because each monomer will have a characteristic conductance change signature);
- 3) repeating steps 1 and 2 for a plurality of similar polymers (col. 4, lines 51-56); and
- 4) determining the order of at least two individual units based upon the information obtained from said plurality of similar polymers (col. 1, line 66 to col. 2, line 8, where the number and composition of monomers that make up an individual polymer is determined, preferably in sequential order; see also col. 6, lines 14-23, where the order of appearance of conductance levels sequentially identifies the monomers of the polymer of DNA).

With regard to claim 131, Church discloses an embodiment of claim 130, wherein the station is a signal generation station (col. 4, lines 31-37, where changes in conductance can identify the monomers in sequence because each monomer will have a characteristic

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conductance change signature and where the signal generated by the interaction between the station and the monomer would meet the limitation of 'signal generation station').

With regard to claim 132, Church discloses an embodiment of claim 130, wherein the station is an interaction station (col. 3, line 66 to col. 4, line 4; see also, col. 1, lines 40-54, where the interface or station interacts sequentially with individual monomers of a polymer and would therefore meet the limitation of 'interaction station' and see col. col. 2, line 21-34, where the measurements can be any measurement, e.g., physical or electrical, that varies with polymer-dependent interaction).

With regard to claim 133, Church discloses an embodiment of claim 130, wherein step 2) comprises measuring an electromagnetic radiation signal generated (col. 3, line 66 to col. 4, line 4; see also, col. 1, lines 40-54, where the interface or station interacts sequentially with individual monomers of a polymer and would therefore meet the limitation of 'interaction station' and see col. col. 2, line 21-34, where the measurements can be any measurement, e.g., physical or electrical, that varies with polymer-dependent interaction).

With regard to claim 134, Church discloses an embodiment of claim 130, wherein the plurality of similar polymers is a homogeneous population (col. 4, lines 51-56).

With regard to claim 135, Church discloses an embodiment of claim 130, wherein the plurality of similar polymers is a heterogeneous population (col. 4, lines 51-56).

With regard to claim 136, Church discloses an embodiment of claim 130, wherein the polymer is a nucleic acid (col. 1, lines 59-62).

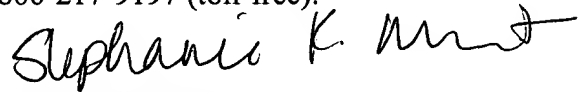
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Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0872. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Stephanie K Mummert
Examiner
Art Unit 1637

SKM


Jeffrey Fredman
Primary Examiner
1/6/06